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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/086,181 | 02/26/2002 | Ruth Gimeno | MNI-220 | 8227 |

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MILLENNIUM PHARMACEUTICALS, INC.
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| EXAMINER | |
|---|---|
| MAYER, SUZANNE MARIE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/086,181 | GIMENO ET AL. | |
| | Examiner | Art Unit | |
| | Suzanne M. Mayer, Ph.D. | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-72* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The examiner and location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1653.

2. Claims 1-72 are pending in this application.

3. It has been determined that the prior restriction requirement of November 29, 2004 was incomplete, hence the need for this second restriction requirement. Any inconvenience is regretted.

### *Election/Restrictions*

4. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods. The methods and agents/products used in the methods, rely upon small molecules, gene therapy vectors, antibodies, anti-sense DNA, ribozymes, DNA molecules or polypeptide molecules used to treat or assay various molecules that are drawn to different diseases and such as aberrant lipogenesis, aberrant lipolysis, obesity, diabetes etc., thereto which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species. Applicant is invited to clearly elect a single Group as it reads on a particular method, the modulators used in the method and the disease treated by the method. The Groups set forth below appear to read on the claims as currently recited, but may be subject to further Restriction and/or species election depending on the claimed recitation.

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 13-20, drawn to a method of identifying a nucleic acid molecule associated with a metabolic disorder, classified in class 435, subclass 6.

II. Claims 10-12 and 21-23, drawn to a method of identifying a polypeptide associated with a metabolic disorder, classified in class 435, subclass 7.1.

III. Claim 24, drawn to a method for identifying a compound capable of treating a metabolic disorder caused by aberrant 14273 nucleic acid expression, classified in class 435, subclass 6.

IV. Claims 24 and 29, drawn to a method for identifying a compound capable of treating a metabolic disorder caused by aberrant 14273 polypeptide activity, classified in class 435, subclass 7.1.

**Note:** If any of groups III-IV is elected, applicant is required to select a specific metabolic disorder to be treated selected from one of claims 25-28 that will be examined along with the elected group

V. Claims 30, 31 and 36, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is a small molecule, classified in class 424, subclass 12.

VI. Claims 30, 36 and 37, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is a gene therapy vector, classified in class 514, subclass 44.

VII. Claims 30, 36, 38 and 39, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is an anti-14273 antibody that can modulate a 14273 polypeptide activity, classified in class 424, subclass 130.1.

VIII. Claims 30, 36, 38 and 40-42, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is a 14273 polypeptide that can modulate a 14273 polypeptide activity, classified in class 514, subclass 12.

IX. Claims 30, 36, 43 and 44, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is a 14273 anti-sense DNA molecule that can modulate 14273 nucleotide expression, classified in class 514, subclass 44.

X. Claims 30, 36, 43 and 45, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is a ribozyme that can modulate 14273 nucleotide expression, classified in class 514, subclass 44.

XI. Claims 30, 36, 43 and 46-48, drawn to a method of treating a subject having a metabolic disorder by administering a 14273 modulator where the modulator is a nucleic acid that can modulate 14273 nucleotide expression, classified in class 514, subclass 44.

**Note:** If any of groups V-XI is elected, applicant is required to select a specific metabolic disorder to be treated selected from one of claims 32-35 that will be examined along with the elected group

XII. Claim 49, drawn to a method for identifying a compound that can modulate an adipocyte activity by assaying the compound to test if it modulates the expression of a 14273 nucleic acid, classified in class 435, subclass 6.

XIII. Claim 49, drawn to a method for identifying a compound that can modulate an adipocyte activity by assaying the compound to test if it modulates the expression of a 14273 polypeptide activity, classified in class 435, subclass 7.1.

**Note:** If any of groups XII-XIII is elected, applicant is required to select a specific metabolic disorder to be treated selected from one of claims 50-52 that will be examined along with the elected group

XIV. Claims 53-54, drawn to a method for modulating an adipocyte activity by contacting an adipocyte with a 14273 modulator, where the modulator is a small molecule, classified in class 514, subclass 1.

XV. Claims 53, 58 and 59, drawn to a method for modulating an adipocyte activity by contacting an adipocyte with a 14273 modulator, where the modulator is an anti-14273 antibody that can modulate a 14273 polypeptide activity, classified in class 424, subclass 130.1.

XVI. Claims 53, 58 and 60-62, drawn to a method for modulating an adipocyte activity by contacting an adipocyte with a 14273 modulator, where the modulator is a polypeptide that can modulate a 14273 polypeptide activity, classified in class 514, subclass 12.

XVII. Claims 53, 63 and 64, drawn to a method for modulating an adipocyte activity by contacting an adipocyte with a 14273 modulator, where the modulator is an 14273 anti-sense DNA molecule that can modulate 14273 nucleic acid expression, classified in class 514, subclass 44.

XVIII. Claims 53, 63 and 65, drawn to a method for modulating an adipocyte activity by contacting an adipocyte with a 14273 modulator, where the modulator is a ribozyme that can modulate 14273 nucleic acid expression, classified in class 514, subclass 44.

XIX. Claims 53, 63 and 64, drawn to a method for modulating an adipocyte activity by contacting an adipocyte with a 14273 modulator, where the modulator is a DNA molecule that can modulate 14273 nucleic acid expression, classified in class 514, subclass 44.

**Note:** If any of groups XIV-XIX is elected, applicant is required to select a specific metabolic disorder to be treated selected from one of claims 55-57 that will be examined along with the elected group.

XX. Claim 69, drawn to a method of modulating glucose production in a cell, classified in class 435, subclass 7.1.

XXI. Claim 70, drawn to a transgenic mouse, classified in class 800, subclass 18.

XXII. Claim 71, drawn to a method of identifying a compound capable of treating a metabolic disorder by administering a compound to a transgenic mouse, classified in class 800, subclass 3.

XXIII. Claim 72, drawn to an isolated cell, or purified preparation of cells from a transgenic mouse, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

6. Inventions I-XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Specifically I-XX are drawn to different methods. In the instant case the different inventions involve completely different methods from assaying nucleic acid expression (I) to assaying polypeptide activities (II), to methods used to treat subjects having a

metabolic disorder by administering proteins, DNA, antibodies, anti-sense DNA, ribozymes or gene therapy vectors. Thus the methods of treatment are drawn to completely different molecules that will have different modes of operation and action in the body. Furthermore, none of these molecules share a common structural feature and would thus require non-coextensive searches.

Groups XXI-XXIII are unrelated because they are drawn to a transgenic mouse, and methods of using a transgenic mouse to perform *in vivo* and *in vitro* testing. Thus the modes of operation and method steps will vary and the methods could be performed with a materially different transgenic animal such as a rabbit.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
30 April, 2005

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653